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*Amendment  
Attorney Docket No. S63.2B-9719-US01*

**Remarks**

This Amendment is in response to the Office Action dated July 7, 2005. Each issue in the office action is discussed below.

***§102 Rejections***

(1)

Claims 21-24, 26, 29 and 30 were rejected under 35 USC §102(e) as being anticipated by Whalen et al. (2002/0107540). It is asserted that Whalen discloses a balloon having a central portion and a plurality of wings including at least one first wing wrapped in a first direction about the central portion of the balloon and at least one second wing wrapped in a second direction opposite the first direction about the central portion of the balloon. It is further asserted that Whalen also teaches a plurality of first wings, a plurality of second wings and T-shaped structures 261 (see figures 4 and 4a).

In Applicant's response to this same rejection in the non-final official action issued on 12/02/04, Applicant disagreed and asserted that the rejection should be withdrawn because, among other reasons, the splines 260 of Whalen et al., which were used as anticipatory disclosure, are not medical balloons, or part of medical balloons, which have a contracted condition and are expandable to an expanded condition. In response, on page 4 in the Response to Arguments section of the presently outstanding Final Official Action, the Examiner states that "the applicant['s] arguments stating that the splines 260 of Whalen et al are not medical balloons, or part of medical balloons, which have a contracted condition and expandable to an expanded condition are not correct because the splines 260 can be inflated or deflated by inflation or deflation of fluid."

The rejection fails because, among other reasons, there is no disclosure indicating that "the splines 260 can be inflated or deflated by inflation or deflation of fluid", as asserted in the official action. In fact, the description of the splines in the reference and the definition of spline are to the contrary.

In addressing the splines, it is stated in paragraph 0049 of the reference that "FIG. 4/4A illustrate bladder engaging elements comprising spaced-apart, preferably padded, splines 260. The padded splines 260 radially extend from the exterior surface of, or are otherwise integral with, the surface of

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the anchor body 264, in this particular configuration, a proximal end portion 54 of the elongate member. The padded splines 260 include, or more particularly radially terminate in, a urinary tract engaging head 261 which provides an increased area for contact with the structures of same, thereby providing a more gentle engagement therewith. As the case with the configuration of FIGS. 3/3A, urine "flow through" may be advantageously achieved."

The description states that the splines are spaced apart and engage the bladder. They are described as padded and extend from the anchor body 264 in the particular configuration shown. The splines 260 have an engaging head 261 to engage the walls of the bladder. The configuration, as shown in figure 4 and 4A, is also stated to allow urine to flow through between the splines. Nowhere does it state that the splines 260 can be inflated or deflated by inflation or deflation of fluid, as asserted in the office action in support of the rejection. There is nothing in the reference that indicates that the splines are anything other than solid pieces radially extending from the anchor body 264 which are shaped to come in contact with the wall of the bladder while at the same time allowing the flow of fluid. The only other discussions of the construction and purpose of the splines, which are found in paragraphs 0051 and 0052, also fail to describe the splines as any thing other than radially extending solid pieces that engage the walls of the bladder. They certainly are not described as being balloon-like and being capable of being inflated or deflated by inflation or deflation of fluid, as asserted in the official action. As such, for the reasons stated above, withdrawal of the rejection is therefore requested because the Whalen et al. fails to disclose each and every element of the claimed invention.

#### *§103 Rejections*

(2)

Claim 25, 39 and 40 was rejected under 35 USC §103(a) as being unpatentable over Whalen et al. in view of Butaric et al. (US 6033380). It is asserted in the official action that Whalen et al. disclose the invention as claimed except for an overlapping relationship between the first wing and the adjacent second wing. However, it is asserted that Butaric discloses a balloon 50 comprising a plurality of wings 70 overlapping with each other and it would have been obvious to modify Whalen by having the wing overlapping with the second wing in view of Butaric to facilitate removal.

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In response Applicant respectfully traverses. Among other reasons, since the rejection depends upon the rejection of paragraph 1 of the official action, it similarly fails for the reasons stated above in response to the rejection of paragraph 1. As such, withdrawal of the rejection is requested.

(3)

Claims 21 and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gaudoin et al. (6,296,655) in view of Hillstead (5,116,318). Gaudoin discloses a balloon 15 comprising a plurality of wings 25 wrapped about the inner tubular member 18. Gaudoin discloses the invention as claimed except for the first wing wrapped in a first direction and the second wing wrapped in a second direction opposite the first direction about the central portion of the balloon. However, Hillstead discloses a balloon having a central portion and a plurality of wings including at least one first wing wrapped in a first direction about the central portion of the balloon and at least one second wing wrapped in a second direction opposite the first direction about the central portion of the balloon. See figures 4 and 8. It would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify Gaudoin by having wings wrapping in opposite direction in view of Hillstead to provide frictional engagement between the outer edges of the wings and the stent.

The rejection fails because, not only does Hillstead fail to provide the asserted disclosure, there is absolutely no motivation to make the combination asserted in the rejection. Only in hindsight of Applicant's disclosure might such a combination be made. The figures pointed out in the rejection, figures 4 and 8, show a cross-section of the devices shown in 3 and 7, respectively. The balloon 34 is shown in its partially deflated shape in figure 2. As can be seen, no predetermined folding condition is shown or discussed. The elastic sleeve 40 around the balloon has a small resting diameter, such that, when it is at rest around the balloon 34, it constricts the balloon 34. There is no teaching regarding the folding of the balloon prior to constriction. The cross-sectional view of figure 4 is merely a random portion of the balloon. There is no mentioned significance of the configuration shown. The same is true for the configuration of the balloon shown in figure 8, which illustrates the balloon *subsequent* to expansion and deflation. The elastic sleeve forces the balloon down when pressure is relieved.

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The configuration of the balloon is given absolutely no significance other than that the flattened "wing-like" portions 21, 22, which are typically formed *after* deflation of the balloon, as shown in figure 1, are held down by the elastic sleeve, as shown in figure 8, for safe withdrawal of the catheter.

Gaudoin et al., on the other hand, deals specifically with folding techniques and configurations. One skill in the art would have no motivation to alter teachings dealing specifically with predilatation balloon folding configurations, as illustrated in Gaudoin et al., based on the disclosure of Hillstead, which offers no predilatation balloon folding teachings. The random cross-sectional configuration pointed out in the official action shows nothing more than the relative positions of the stent 32, the elastic sleeve 40 and the balloon 34 and that the elastic sleeve forcibly constricts the balloon. As such, the asserted combination lacks sufficient motivation to support a *prima facie* case and withdrawal of the rejection is respectfully requested.

The claims are now believed to be in condition for allowance. The prompt allowance of these claims is earnestly solicited. If the Examiner wishes to discuss further issues, he is invited to contact the undersigned.

Respectfully submitted,

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